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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,046	01/12/2001	Edith Mathiowitz	BU 111	1885

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EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/760,046	Applicant(s) MATHIOWITZ ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment B, and the Formal Drawings, both received by the Office on September 16, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4,and 6-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,817,343 to Burke.

Burke teaches a method for forming polymer/ drug microparticles comprising the steps of (1) forming a polymer/ drug mixture comprising a polymer dissolved in an organic solvent and a suspended labile drug; (2) removing the solvent by freezing and extracting the solvent (abstract). Additionally, Burke teaches that the solvent is extracted through lyophilization (c 13, claim 21). Additionally, Burke teaches that the polymer can be a biocompatible polymer, such as poly(lactic acid), poly(lactic acid-co-glycolic acid) copolymer, poly(caprolactone), polycarbonates, polyamides, polyanhydrides, poly(amino acids), polycyanoacrylates, and polyurethanes (c 12, claim 11). Furthermore, Burke teaches that the drug can be a growth factor, a peptide, a polypeptide, or a polynucleotide (c 12, claim 3).

Burke does not teach applicant's specific range of particle sizes, or particular ranges of solvent to non-solvent. However, it is the position of the examiner that because applicant and Burke discuss the same process, the particular size range and particular ratios are manipulatable parameters, known to the ordinary worker as the part of the process of normal optimization. One of ordinary skill in the art would have been motivated to manipulate the ratios and particle sizes to achieve the best result, depending on the drug to be administered. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that Burke requires a milling or grinding step to reduce the size of the particles, while Applicant's method micronizes the particles while the agent is dissolved in solution with the matrix material. The examiner does not find the argument persuasive, because Applicant's current claim language is open (comprising), and therefore does not exclude any additional steps which are not specifically stated in the claim. Therefore, Applicant's method claims do not prohibit the use of grinding or milling step. Furthermore, Applicant's instant claims do not state that the micronization step occurs when the agent is dissolved in solution. It is recommended that if this is a special feature to applicant's claimed invention, this limitation should be more explicitly set forth in the instant claims.

Applicant also argues that Burke does not teach Applicant's claimed size for the particles. This argument is also found to be unpersuasive. As stated in the prior action, particular size ranges and ratios are well known manipulatable parameters, known to the ordinary worker as

part of the process of normal optimization. Furthermore, there is no evidence that the particles of Burke do not fall within Applicant's claimed range. The burden is shifter to Applicant to compare the particles of Burke with Applicant's claimed particles to show any difference in the sizes. Absent this scientific evidence, the above rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A.E. Pulliam
Patent Examiner
Art Unit 1615
December 6, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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